

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Deborah A. Evrard, et al.

Confirmation No.: Not Yet Assigned

Application No.: 10/659,160

Group Art Unit: Not Yet Assigned

Filing Date: September 10, 2003

Examiner: Not Yet Assigned

For: ANTIDEPRESSANT PIPERIDINE DERIVATIVES OF HETEROCYCLE-FUSED BENZODIOXANS

DATE OF DEPOSIT:

*January 27, 2004*

I HEREBY CERTIFY THAT THIS PAPER IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID, ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE UNITED STATES PATENT AND TRADEMARK OFFICE, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450.

TYPED NAME: Elizabeth A. McLoud

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

## INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 CFR § 1.56 and in accordance with 37 CFR §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 CFR § 1.56(b).

In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of

the above identified application as set forth in § 1.491, before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of request for continued examination under § 1.114, no additional fee is required.

- In accordance with § 1.129(a), this Information Disclosure Statement is being filed in connection with  the first or  second After Final Submission, therefore:
  - Certification in Accordance with § 1.97(e) is attached; or
  - The fee of \$180.00 as set forth in § 1.17(p) is attached.
- In accordance with § 1.97(c), this Information Disclosure Statement is being filed after the period set forth in § 1.97(b) above but before the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311, or before an action that otherwise closes prosecution in the application, therefore:
  - Certification in Accordance with § 1.97(e) is attached; or
  - The fee of \$180.00 as set forth in § 1.17(p) is attached.
- In accordance with § 1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with § 1.97(e); and the submission fee of \$180.00 as set forth in § 1.17(p).
- Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

- Copies of references listed on the attached Form PTO-1449 are enclosed herewith
- Copies of references listed on the attached Form PTO 1449 are not required to be submitted pursuant to the June 30, 2003 recent revisions to 37 CFR § 1.98(a)(2)(i).

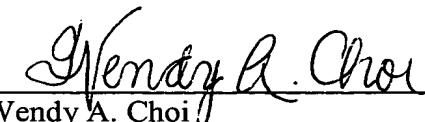
EXCEPT THAT:

- In view of the voluminous nature of references 3, 5, 7, 8, 9, 14, and 17, and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.
- In accordance with § 1.98(d), copies of the following references listed on the attached Form PTO-1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application:
  - Copies of references [list as appropriate] listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior Application No. , filed

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050. This form is submitted in duplicate.

- The relevance of those listed references which are not in the English language is as follows:
- There are no listed references which are not in the English language.

Date: January 27, 2004

  
\_\_\_\_\_  
Wendy A. Choi  
Registration No. 36,697

WOODCOCK WASHBURN LLP  
One Liberty Place - 46th Floor  
Philadelphia, PA 19103  
Telephone: (215) 568-3100  
Facsimile: (215) 568-3439

© 2003 WW



<b>Form PTO-1449 Modified</b> List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office		Docket No. WYNC-0328/ AM101204(NP)	Application No. 10/659,160
		Applicant Deborah A. Evrard, et al.	
		Filing Date September 10, 2003	Group Not Yet Assigned
		Confirmation No. Not Yet Assigned	
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
	<b>1</b>	Artigas, F., et al., "Pindolol induces a rapid improvement of depressed patients treated with serotonin reuptake inhibitors," <i>Arch Gen Psychiatry</i> , March 1994, 51, 248-251	
	<b>2</b>	Blier, P., et al., "Effectiveness of pindolol with selected antidepressant drugs in the treatment of major depression," <i>J. of Clinical Psychopharmacology</i> , 1995, 15(3), 217-222	
*	<b>3</b>	Bundgaard, (Ed.), <i>Design of Prodrugs</i> , Elsevier, 1985	
	<b>4</b>	Bundgaard, H., "Means to enhance penetration; Prodrugs as a means to improve the delivery of peptide drugs," <i>Advanced Drug Deliver Reviews</i> , 1992, 8, 1-38	
*	<b>5</b>	Bundgaard, <i>J. of Pharmaceutical Sciences</i> , 1988, 7(285 et seq.)	
	<b>6</b>	Cheetham, S.C., et al., "[ <sup>3</sup> H]paroxetine binding in rat frontal cortex strongly correlates with [ <sup>3</sup> H]5-HT uptake: effect of administration of various antidepressant treatments," <i>Neuropharmacol.</i> , 1993, 32(8), 737-743	
*	<b>7</b>	Eliel, E.L., <i>Stereochemistry of Carbon Compounds</i> , McGraw-Hill, NY, 1962	
*	<b>8</b>	Higuchi, et al. (Eds.), <i>Prodrugs as Novel Drug Delivery Systems</i> , American Chemical Society, 1975	
*	<b>9</b>	Jacques, et al., <i>Enantiomers, Racemates and Resolutions</i> , Wiley Interscience, NY, 1981	
	<b>10</b>	Krosgaard-Larsen, et al. (Eds.), "Design and Application of Prodrugs," <i>Textbook of Drug Design and Development</i> , 1991, Chap. 5, 113-191	
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>	

\* A copy of these references will not be forwarded to the U.S. Patent and Trademark Office since they are believed to be too voluminous and easily obtainable by the Examiner.



<p><b>Form PTO-1449 Modified</b></p> <p><b>List of Patent and Publications Cited by Applicant (Use several sheets if necessary)</b></p> <p><b>U.S. Department of Commerce Patent and Trademark Office</b></p>		<p>Docket No. WYNC-0328/ AM101204(NP)</p> <p>Application No. 10/659,160</p>	
		<p>Applicant Deborah A. Evrard, et al.</p>	
		<p>Filing Date September 10, 2003</p>	<p>Group Not Yet Assigned</p>
		<p>Confirmation No. Not Yet Assigned</p>	
<p><b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b></p>			
	11	Lazareno, S., et al., "Pharmacological characterization of acetylcholine-stimulated [ <sup>3</sup> S]-GTPγS binding mediated by human muscarinic m1-m4 receptors: antagonist studies," <i>Br. J. Pharmacol.</i> , 1993, 109, 1120-1127	
	12	Ostrowski, S., "A synthesis of fused pyrimidine mono-n-oxides," <i>Heterocycles</i> , 1996, 43(2), page 389-396	
	13	Perez, V., et al., "Randomised, double-blind, placebo-controlled trial of pindolol in combination with fluoxetine antidepressant treatment," <i>The Lancet</i> , May 31, 1997, 349, 1594-1597	
*	14	Remington's Pharmaceutical Sciences, 17 <sup>th</sup> Ed., Gennaro, A.R. (Ed.), <i>Mack Publishing Company, Easton, PA</i> , 1985	
	15	Tome, M.B., et al., "Serotonergic autoreceptor blockade in the reduction of antidepressant latency: personality variables and response to paroxetine and pindolol," <i>J. Affect Disord</i> , 1997, 44, 101-109	
	16	Tome, M.B., et al., "Paroxetine and pindolol: a randomized trial of serotonergic autoreceptor blockade in the reduction of antidepressant latency," <i>Int. Clin. Psychopharmacol</i> , 1997, 12, 81-89	
*	17	Widder, et al. (Eds.), <i>Methods in Enzymology</i> , <i>Academic Press</i> , 1985, Vol. 4	
	18	Wilen, S.H., "Tables of Resolving Agents and Optical Resolutions," <i>Univ. of Notre Dame Press, Notre Dame, IN</i> , E.L. Eliel (Ed.), 1972, page 268-298	
	19	Wilen, S.H., et al., "Strategies in optical resolutions," <i>Tetrahedron</i> , 1977, 33, 2725-2736	
<p><b>EXAMINER</b></p>		<p><b>DATE CONSIDERED</b></p>	

\* A copy of these references will not be forwarded to the U.S. Patent and Trademark Office since they are believed to be too voluminous and easily obtainable by the Examiner.